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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,792	12/13/2001	San-Yup Lee	HYLEE60.001APC	5798

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,792

Applicant(s)

LEE ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 ~~is/are~~ pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 121301.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

- 1) Acknowledgment is made of Applicants' preliminary amendments 12/13/01, 10/29/02, 10/20/03, 03/01/04 and 09/13/04. With this, Applicants have amended the specification.

It is noted that the amendment and papers filed 10/20/03 are not signed by the attorney of record.

Election

- 2) Acknowledgment is made of Applicants' election filed 06/08/04, with traverse, of invention II, claims 3-6, in response to the written lack of unity mailed 05/07/04. Applicants' contend that SEQ ID NO: 1 codes for the two specific structural elements: a specific His tag sequence (AGP) and a specific protease target sequence for Factor X (IEGR), and therefore SEQ ID NO: 1 contains 13 amino acids. Applicants state that SEQ ID NO: 28 codes for a single structural element, the same specific protease target sequence from SEQ ID NO: 1 (IEGR). Applicants assert that SEQ ID NO: 26 codes for the same two structural elements of SEQ ID NO: 1 and thus codes for SEQ ID NO: 28, that is the specific HIS tag and the specific protease target sequence. Applicants state that SEQ ID NO: 26 codes for two additional structural elements: an endoxylanase signal sequence and the N-terminal portion of the mature hG-CSF polypeptide. In essence, Applicants argue that the product of claim 3, as amended, includes the structural elements of the product of invention I.

Applicants' arguments have been carefully considered. Upon further consideration, the lack of unity set forth in the Office Action mailed 05/07/04 is hereby withdrawn. Claims of invention I, i.e., claims 1, 2 and 7-10 have been combined with the elected claims 3-6 of invention II. Claims 1-10 and the new claims 11-13 have been examined.

Status of Claims

- 3) Claim 2 has been amended via the amendments filed 10/20/03 and 03/01/04.

Claim 3 has been amended via the amendment filed 09/13/04.

New claims 11-13 have been added via the amendment filed 09/13/04.

Claims 1-13 are pending and are under examination. A First Action on the Merits on these claims is issued.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicants' information disclosure statement filed 12/13/01. The information referred to therein has been considered and a signed copy is attached to this Action.

Sequence Listing

- 5) Acknowledgment is made of Applicants' CRF and the raw sequence listing, which have been entered.

Priority

- 6) The instant application is national stage 371 application of PCT/KR01/00549 filed 03/31/01 and claims foreign priority to application 2000/17052 filed 03/31/00 in Republic of Korea. It is noted that a certified copy of the foreign priority document 2000/17052 has yet not been submitted to the Office.

Specification - Informalities

- 7) The instant specification is objected to for the following reason(s):
The amendment introduced to the first paragraph of the specification via the preliminary amendment filed 12/13/01 is confusing in the recitation: 'This is the U.S. National Phase under 35 U.S.C 371'. It is suggested that Applicants insert the word --application-- after the recitation 'Phase'.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

- 8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:
The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.
- 9) Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.
- (a) Claim 2 lacks proper antecedence in the limitation: 'an oligopeptide' (see line 2). Since claim 2 depends from claim 1, which already recites 'an oligopeptide', it is suggested that Applicants replace the limitation with --the oligopeptide--.
- (b) Claim 2 fails to distinctly claim the subject matter and is confusing or redundant in the limitations: 'of claim 1, wherein the nucleotide sequence codes for an oligopeptide which comprises an amino acid sequence of isoleucine-glutamic acid-glycine-arginine (Ile-Glu-Gly-Arg;

SEQ ID NO: 28)'. For clarity and for the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the phrase with --of claim 1, wherein the nucleotide sequence coding for the oligopeptide comprises the amino acid sequence of SEQ ID NO: 28--.

(c) Claim 3 is indefinite in the recitation 'represented in Figure 13', because it fails to point out what is included or excluded by the claim language. According to M.P.E.P 2173.05(s), where possible, claims are to be complete in themselves. Incorporation by reference to Tables, Figures, or Examples as in this case, is a necessity doctrine, not for Applicants' convenience. See *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993). Furthermore, Figure 13 is subject to changes via amendments, and such amendments to the Figure would potentially change the scope of the claim. In order to obviate the rejection, it is suggested that Applicants delete the limitation 'represented in Figure 13' from claim 3, since it is unnecessary.

(d) Claim 4 is redundant in the limitation: 'microorganism, *E. coli*'. It is suggested that Applicants replace the limitation with --*E. coli*--.

(e) Claim 5 is confusing and/or redundant in the limitation: 'microorganism of claim 4, wherein the *E. coli* is'. It is suggested that Applicants replace the limitation with --*E. coli* of claim 4--.

(f) Claim 3 is vague and indefinite in the limitation 'derived', because it is unclear what is encompassed in this limitation. Does the process of 'deriving' encompass: extraction, isolation, recombinant production, separation, purification, modification, or expression on cell surface? It is suggested that Applicants delete the limitation since it is unnecessary.

(g) Claims 3 and 12 are vague and indefinite in the limitation 'modified gene', because it is unclear in what way the gene is modified. What constitutes a 'modified gene' and how much of the gene's original structure has to be retained such that the resulting product can be considered a 'modified gene' is not clear. The metes and bounds of the structure encompassed in the limitation 'modified gene' are indeterminate.

(h) Claim 8 is confusing in the limitations: 'process of claim 7, wherein the plasmid vector of claim 1 is pTHKCSFmII'. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the recitation with --process of claim 7, wherein the plasmid vector is pTHKCSFmII--.

(i) Claim 9 is indefinite and confusing in the limitations: 'fusion protein is obtained from the culture by employing Ni-column'. It is unclear how a fusion protein can be obtained from a bacterial culture containing transformed *E. coli* cells by employing Ni-column. Is the whole bacterial culture subject to Ni-column chromatography?

(j) Claims 12 and 13 are vague and indefinite in the recitation 'nucleotides of SEQ ID NO:...' without reciting that SEQ ID NO: represents a nucleotide sequence. In order to distinctly claim the subject matter of the instant invention and to be consistent with the claim language used in line 2 of claim 11, it is suggested that Applicants replace the recitation with --nucleotides of the nucleotide sequence of SEQ ID NO:--.

(k) Claim 6 is vague in the limitation: '*E. coli* (KCTC 0754BP) transformed' because it is unclear what does '(KCTC 0754BP)' stand for. If this is a deposit accession number, for clarity, it is suggested that Applicants replace the recitation with --*E. coli* deposited as KCTC 0756BP, wherein said *E. coli* is transformed--.

(l) Claim 1 is vague, indefinite and confusing in the limitation: 'consisting of 13 amino acids including', because it is unclear whether a closed claim language or an open-ended claim language is intended.

(m) Claims 2, 4-6 and 8-13, which depend from claim 1, 3 or 7, are also rejected as being indefinite because of the indefiniteness identified in the base claim.

Objection(s)

10) Claims 6 and 8 are objected to for the following reasons:

(a) Claim 8 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

(b) Claim 6 is objected to for not italicizing the recitation '*E. coli*'.

Remarks

11) Claims 1-13 stand rejected. Instant claims are free of prior art currently of record.

12) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with

the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

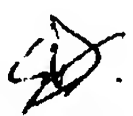
13) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

November, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER